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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,728	06/27/2005	Thomas Julius Borody	119381-00002 / 3703US	7029

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EXAMINER	
HOLT, ANDRIAE M	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,728	BORODY ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 34-39* is/are pending in the application.

4a) Of the above claim(s) *12-18 and 34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/31/2008*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed October 31, 2008. Claims 1-18 and 34-39 are pending in the application. Claim 1 has been amended. Claims 12-18 and 34-36 have been withdrawn. Claims 19-33 have been cancelled. Claims 1-11 and 37-39 will be examined on the merits.

Information Disclosure Statement

The Information Disclosure Statement filed October 31, 2008 is acknowledged.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

The rejection of claims 1-7 and 39 are 35 U.S.C. 102(b) as being anticipated by Wolf et al. (WO 01/67895) is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. (WO 01/67895).

Wolf et al. disclose a two component carbohydrate mixture which blunts the postprandial glycemic response of digestible glucose polymers. The two component

carbohydrate mixture is optionally admixed with nonabsorbent carbohydrates, fiber and indigestible oligosaccharides to form a carbohydrate system for diabetics (Abstract).

Wolf et al. disclose in Table 6, page 19, the Bill of Materials for Unflavored Liquid Nutritional:

Fructose 28 Kg

Fructooligosaccharide 4.607 Kg (minimally degradable sugar 1 to 3 times the weight of sodium salt, instant invention)

Magnesium chloride 2.4 Kg (magnesium salt 0.1 to 10 times the weight of sodium salt, instant invention)

Sodium citrate 1.18 Kg (sodium salt, sodium citrate, instant invention)

Potassium citrate 1.146 Kg (potassium salt 0.05 to 1 times the weight of sodium salt, instant invention)

Sodium hydroxide 1.134 Kg (sodium salt, instant invention)

Magnesium phosphate 1.028 Kg (magnesium salt 0.1 to 10 times the weight of sodium salt, magnesium phosphate, instant invention)

Vitamin C 584 gm (nutritional element, vitamin C, instant invention)

Potassium chloride 530 gm (potassium salt, potassium chloride 0.05 to 1 times the weight of sodium salt, instant invention)

Vitamin E 99 gm (nutritional element, vitamin E, instant invention)

Vitamin DEK premix 65.34 gm (nutritional element, vitamin D, E and K, instant invention)

Folic acid 0.64 gm (nutritional element, folic acid, instant invention)

Vitamin A 8.04 gm (nutritional element, vitamin A, instant invention).

Wolf et al. disclose that the liquid nutritional products of the present invention have been manufactured by preparing four slurries which are blended together, heat treated, standardized, packaged and sterilized. Wolf et al. disclose the process for manufacturing 1000 kilograms of a liquid nutritional product, using the bill of materials from Table 6 (page 20, lines 1-4) (soup or soup like form, instant invention).

Wolf et al. disclose a carbohydrate/mineral slurry is prepared by first heating about 82 kilograms of water to a temperature of from about 65º C to about 71 º C with agitation. Wolf et al. further disclose that with agitation, the required amount of sodium citrate and gellen gum under the product name "Kelcogel®" is added and agitated for 5 minutes. Wolf et al. disclose that the required amount of the ultra trace mineral/trace mineral (UTM/TM) premix is added. Wolf et al. disclose that agitation is maintained until the minerals are completely dispersed. Wolf et al. disclose with agitation, the required amounts of the following minerals are then added: potassium citrate, potassium chloride, chromium chloride; magnesium chloride and potassium iodide. Wolf et al. disclose that next, the first maltodextrin, "Maltrin® M-100" and fructose are added to slurry under high agitation, and are allowed to dissolve. Wolf et al. further disclose that with agitation, the required amounts of maltitol powder, Maltisorb® Powder P35SK, maltitol syrup, Hystar® 5875, fructooligosaccharides, "Nutriflora-P® Fructo-oligosaccharide Powder (96%)" and a second maltodextrin, Fibersol® 2(E) are added and agitated well until completely dissolved. Wolf et al. disclose the required

amount of micronized tricalcium phosphate is added to the slurry under agitation (page 20, lines 1-25).

Wolf et al. disclose artificial sweeteners may also be added to the nutritional formula to enhance the organoleptic quality of the formula (page 17, lines 27-28). Wolf et al. further disclose the nutritional products of the present invention will also include a flavoring and/or color to provide the nutritional products with an appealing appearance and an acceptable taste for oral consumption (page 17, lines 29-32) (flavoring ingredient, instant invention).

All of the limitations of claims 1-7 and 39 are met by Wolf et al.

Response to Arguments

Applicant's arguments filed October 31, 2008 have been fully considered but they are not persuasive. Applicant argues that the composition taught by Wolf et al. contains 5 times the minimally degradable sugar in the composition because Fibersol 2(E) is by applicant's definition a minimally degradable sugar and the combination of fructoogliosacchride and Fibersol 2(E) is higher than the 1 to 3 times the weight of sodium salt in the composition.

In response to Applicant's arguments, independent claim 1 calls for at least one water soluble minimally degradable sugar in the composition that is 1 to 3 times the weight of the sodium salt in the composition. Wolf et al. discloses that at least one of the minimally degradable sugars, the fructoogliosaccharide, is 1 to 3 times the weight of the sodium salt in the composition. The claim does not read that the total number of minimally degradable sugars has to be 1 to 3 times the weight of the composition.

Therefore, Wolf et al. meet all the limitations of claims 1-7 and 39 and thereby anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 8-11, and 37-38 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kawakami (JP 05306221) in view of Colliopoulos (US 5,232,699) in further view of Cockerill (US 4, 452,779).

Applicant's Invention

Applicant claims a composition comprising at least one water-soluble sodium salt; at least on water-soluble minimally degradable sugar, at least on water-soluble

potassium salt and at least on water-soluble magnesium salt. Applicant claims the minimally degradable sugar is xylose. Applicant further claims the water-soluble sodium salt is sodium chloride, the water soluble potassium salt is potassium chloride and the water-soluble magnesium salt is magnesium sulfate.

Determination of the scope of the content of the prior art (MPEP 2141.01)

Kawakami teaches an intestinal tract penetrant remover solution which contains 32.3 to 35.7 gm of magnesium citrate (magnesium salt, magnesium citrate 0.1 to 10 times weight of sodium salt, instant invention) in 900 ml of an aqueous solution of sodium chloride 4.8 to 5.4 mmol (sodium salt, sodium chloride, instant invention), potassium hydroxide 8.5 to 9.3 mmol (potassium salt, 0.05 to 1 times weight of sodium salt, instant invention) and sugars 10.7 to 2.1 gm (sugar, 1 to 3 times the weight of sodium salt, instant invention). Kawakami teaches the composition has a final osmotic pressure of 290 to 310 mOsm/L. Kawakami teaches that osmotic pressure in the range of 290 to 310 mOsm/L is an osmotic pressure range which can be used safely and effectively as an intestinal tract penetrant remover without producing both absorption of moisture by body fluid and drying from the body fluid from an intestinal tract. Kawakami teaches the composition is used for intestinal diagnosis such as colonic endoscopy and x-ray graphy (method of inducing purgation of the colon, instant invention). Kawakami teaches the composition show similar rinsing effect as isotonic magnesium citrate solution and causes no electrolyte imbalance (Abstract).

Kawakami teaches in the example the preparation of the intestinal tract penetrant solution. Kawakami teaches that disintegration of the mixed liquor is dried and carried

out and that 290 kg of dry articles are obtained. Kawakami teaches that 102.8 kg of white soft sugar is added to the obtained powder. Kawakami further teaches the mixture is filled up to 50 gm per bundle with an automatic filling machine. Kawakami teaches that it is the osmotic pressure about 300 mOsm/L which dissolved the pharmaceutical preparation at 50 gm per 1 bundle in water, and was set to 900 mL, in spite of the content of potassium ion and chloride ion.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Kawakami does not teach the minimally degradable sugar is xylose of claims 2 and 37-38. Kawakami does not teach the purgative comprises a hypertonic aqueous solution of claim 8. Kawakami also does not teach the water-soluble magnesium salt is magnesium sulfate of claim 38.

Colliopoulos teaches laxative compositions containing sennosides and psyllium, wherein sennoside is dispersed in a palatable food grade fat having a melting point within the range of from about 30º C to about 50 º C., and to methods for treating constipation by ingesting compositions of the present invention (Abstract). Colliopoulos teaches optional components suitable for ingestion include: other dietary fiber (especially insoluble dietary fiber); shortening; flour; sweetening agent; and flavoring agent (col. 2, lines 62-65). Colliopoulos teaches the sweetening agents include water-soluble sweetening agents such as monosaccharides, disaccharides, and polysaccharides such as xylose, ribose, glucose, mannose, galactose, fructose, dextrose, sucrose, maltose, partially hydrolyzed starch or corn syrup solids and sugar alcohols such as sorbitol, xylitol, mannitol and mixtures thereof (col. 6, lines 51-61).

Cockerill teaches a composition comprising a combination of diuretic and cathartic components in proportions which maintain the electrolyte balance so as to avoid dehydration of the mammal while effectively removing excess fluid from mammary tissue via the kidneys and the intestinal tract and which in a preferred form is comprised on a weight basis of 65 percent sodium sulfate, 13 percent magnesium sulfate monohydrate, 12 percent sulfur and 10 percent anhydrous potassium sulfate (Abstract).

Cockerill teaches a suitable saline cathartic or laxative component can be selected from the group comprising potassium sulfate, potassium chloride, sodium sulfate, sodium chloride, sodium phosphate, sodium tartrate, sodium citrate, magnesium sulfate (claim 38, magnesium sulfate, instant invention) magnesium phosphate, magnesium oxide, magnesium hydroxide, magnesium tartrate, and magnesium carbonate (col. 2, lines 19-25). Cockerill teaches the compounds which are less readily absorbed are preferred for use as the saline cathartic component of the composition and for providing a hypertonic solution in the intestinal tract (col. 2, lines 25-29). Cockerill teaches the saline cathartics preferably form a hypertonic solution in the intestine and the water draining into the intestine by osmotic pressure significantly increases the liquid bulk within the intestine which has an effect similar to other bulk cathartics or laxatives (col. 2, lines 29-34) (claim 8, hypertonic aqueous solution, instant invention). Cockerill further teaches where a large amount of a bulking agent is used in combination with the composition the amount of the cathartic used in the composition can be reduced (col. 2, lines 34-37). Cockerill teaches the magnesium

sulfate, while having saline laxative properties, is used primarily as a source of magnesium to prevent hypomagnesia which otherwise would result due to the diuretic effect of the sodium sulfate and potassium sulfate components of the composition (col. 3, lines 28-33)

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Kawakami, Colliopoulos, and Cockerill and use xylose as the minimally degradable sugar in the composition. One skilled in the art at the time the invention was made would have been motivated to use xylose as the minimally degradable sugar because Colliopoulos teaches that xylose, glucose, and fructose are used as sweetening agents in laxatives. Therefore, the skilled artisan would have been motivated with a reasonable expectation of success to use xylose in the composition as taught by Kawakami at the same ratios because xylose, glucose, and fructose are functionally equivalent sweetening agents for laxative compositions.

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Kawakami, Colliopoulos, and Cockerill and use magnesium sulfate as the water-soluble magnesium salt in a hypertonic solution. One skilled in the art at the time the invention was made would have been motivated to use the magnesium sulfate because Cockerill teaches that magnesium sulfate while having saline laxative properties, is used primarily as a source of magnesium to prevent

hypomagnesia which otherwise would result due to the diuretic effect of the sodium salt and potassium salt components of the composition.

One skilled in the art at the time the invention was made would also have been motivated to produce a hypertonic solution with a reasonable expectation of success as Cockerill teaches saline cathartics, magnesium sulfate, preferably form a hypertonic solution in the intestine and the water draining into the intestine by osmotic pressure significantly increases the liquid bulk within the intestine which has an effect similar to other bulk cathartics or laxatives. Given the state of the art as evidenced by the teachings of the cited references, and absent any evidence to the contrary there would be a reasonable expectation of success in combining the teachings of the cited references to produce a good tasting laxative composition that can be used safely and effectively as purgative without depleting the body of essential electrolytes, causing dehydration and other side effects associated with electrolyte purgative.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

None of the claims are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616